IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION 2:07-cv-3770-DMC-MF

ELI LILLY AND COMPANY,	TRANSCRIPT OF PROCEEDINGS
Plaintiff,	M O T I O N
-vs-	Pages 1 - 95
ACTAVIS ELIZABETH, LLC, et als,	
Defendants.	

Newark, New Jersey
May 5, 2010

B E F O R E: HONORABLE MARK FALK,
UNITED STATES MAGESTRATE JUDGE

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Pursuant to Section 753 Title 28 United States Code, the following transcript is certified to be an accurate record as taken stenographically in the above entitled proceedings.

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THE COURT: All right. This is the case of Eli Lilly versus Actavis, et al. It's docket 07-3770.

Would counsel please place their appearances on the record.

MS. MASUROVSKY: Good morning, your Honor. Laura Masurovsky for Eli Lilly & Company. And together with me are my colleagues, Charlie Lipsey, from Finnegan; John Brenner, from Pepper Hamilton; and Mark Stewart, from Eli Lilly; and my colleague, Mr. Holtman, from Finnegan; and Mr. Barker, from Finnegan.

THE COURT: Good morning.

MR. BARKER: Good morning, your Honor.

MR. CLEMENT: Good morning, your Honor. My name is Alan Clement. I'm from the law firm of Locke Lord Bissell & Liddell on behalf of defendant Apotex. And with me is my partner Andrea Wayda from our New York office; Joe Froehlich from our New York office; and Myoka Goodin, from our Chicago office.

MS. FLAX: Good morning. Melissa Flax from Carella Byrne on behalf of Aurobindo.

MR. RAKOCZY: And William Rakoczy, your Honor, also on behalf of Aurobindo. Good morning, your Honor.

MR. PARKER: Good morning, your Honor. Tom Parker from the law firm of Austin & Bird, representing Mylan Pharmaceuticals; here with our local counsel, Arnie Calmann

from the Saiber Law Firm.

MR. CALMANN: Good morning, your Honor.

MR. ABRAHAM: Good morning, your Honor, Eric Abraham from Hill Wallach, on behalf of defendant Sandoz.

MR. RICHTER: Good morning, your Honor. James Richter on behalf of the Sun Pharmaceuticals. There on the phone is Gail Standish on behalf of Sun.

MR. CALMANN: Good morning. Let me not forget my colleague, Katherine Escanlar, also for Mylan.

THE COURT: Good morning.

All right, welcome. Before the Court is an In Limine motion to exclude or to deal with the issue of Dr. Steven Paul. This has been the subject of some prior discussion on the record and off the record. We know that the trial in this case is going to proceed, I believe, on the 18th of May; and we had the final pretrial a couple of weeks ago at the final pretrial. The final pretrial I think was delivered to the Court the day of the pretrial, and the In Limine motions were not very specifically identified. At the final pretrial I asked counsel if there were any In Limine motions that addressed or dealt with discovery issues, which normally I would handle for Judge Cavanaugh. And at that time Miss Masurovsky, I think, raised immediately the issue of Dr. Paul replacing, or I guess the plaintiff's position is Dr. Paul replacing Dr. Watanabe as a witness at trial. Of course the defendants take the position

that that's not really the case.

I directed that the plaintiffs provide a detailed proffer of what Dr. Paul was expected to testify to and we set a briefing schedule. I've gotten extensive briefing, which we have read and poured over, as well as extensive declarations from both sides.

There was also a telephone call when I was under the -- had the understanding that there were also a lot of documents in dispute. And during that call we discussed the issue on this motion. I ordered that we appear here for oral argument. There were many questions that were raised. There were sharp disputes about many of the issues. And I thought it best, given the importance, and given how strongly everyone felt about this, to come in and argue it on the record and get it decided.

So I think I'd like to begin -- of course I'll hear from you on the motions, but I think the first thing that I would like to do, and I'm going to address it to plaintiffs, is to try to get a clearer picture about what the plaintiffs wish Dr. Paul to testify to because there was, I think, a three-page or four-page proffer. And the defendants have taken the position that that is not -- or that what's in the proffer is not really accurate, and that what plaintiff is trying to do is something different than seems to be described, at least in the words, the actual words of the proffer.

So I think I'd like to hear from you on that, Miss Masurovsky.

MS. MASUROVSKY: Thank you, your Honor.

To put the testimony in context, Lilly's identification of Dr. Paul as a replacement for Dr. Watanabe occurred as quickly as it could after the Court's denial of our motion for re-consideration on the issue of the invalidity and -- I'm sorry, the non-enablement issue that plaintiffs -- defendants, excuse me, had raised. And I think it would be useful if the Court will permit me, if I may handle the timeline, to put it all in context.

THE COURT: That's fine.

MS. MASUROVSKY: And I will give, of course, defendants a copy to follow along. I have made a few.

If I may approach?

THE COURT: Sure.

MS. MASUROVSKY: I made a few slides of the points that I would like to make in my answering of your questions, your Honor.

THE COURT: Okay.

MS. MASUROVSKY: And in our argument today. And the timeline, which is the first slide, I hope, that you have.

THE COURT: Yes.

MS. MASUROVSKY: Here, I'm sorry, let me get you all another copy.

There were really four distinct phases of this case, and the most important thing about where Steve Paul's testimony comes into play and in lieu of Dr. Watanabe's, is in the context of the issue that defendants have raised on non-enablement, on which they have the burden of proof. Of course, as the Court knows, the only issue on which Lilly had the burden of proof was infringement, and Judge Cavanaugh decided that issue in our favor and infringement is no longer on the table. The sole issues at trial, they have the burden of proof on all of them, all of our validity and unenforceability issues. So we're in a responsive mode, even though we're technically the plaintiff, they're attacking the patent so we respond to them.

And what's important to understand about their non-enablement argument, their attack on the patent for lack of enablement, is that they did not actually disclose their underlying allegations until after the close of discovery. So in this first phase on the left hand side of the timeline, which is basically in yellow, all the way through their first set of answers to our interrogatories asking for what their contentions were and what their defenses were on this non-enablement Section 112 issue, they referred us to their notice letter. And their notice letter had nothing about Section 112. So we knew nothing about any non-enablement position that they had all the way through this timeline

section on the left.

Then -- that was in 2007. And then in 2008, there were more exchanges of discovery, depositions of 30(b)(6)s, and individual depositions, including Dr. Watanabe's deposition, Dr. Spencer, Dr. Heiligenstein, the third parties who conducted the Mass General testing, the many Lilly 30(b)(6) witnesses on Lilly's development of atomoxetine for ADHD, Lilly's business, et cetera. And it wasn't until after all of those depositions were concluded, and after the close of fact discovery, and after Lilly had supplemented its answers to interrogatories on November 24th, 2008, did we, Lilly, receive the very first explanation of their non-enablement under Section 112 position.

So wholly apart from the fact that it would not have been good litigation technique to take Dr. Watanabe's full trial testimony during my adversary's deposition of him, we didn't even know what their non-enablement position was at the time of his deposition, so it would have been impossible, even if I had chosen to do it, to ask him those questions.

We get their response on November 24th, 2008. That's the bottom blue box. And we take a look at their explanation of what it is. And we see that it contradicts 60 years of Federal Circuit legal precedent. And we say they have no colorable claim, no legal basis for their contention that if you don't have clinical trial results before you file the patent application, you don't have an enabled patent, and that

you couldn't use the very results that Mass General's testing gave us to prove enablement. We said: That's ridiculous. I don't know where they're getting that. Some district court may have held something like that, but that contradicts controlling Federal Circuit precedent. They're wrong, and so we felt we proved that.

And, in fact, when they moved for summary judgment, and that's in this third phase in, I guess tan, if that's the way to describe that color, beginning with the May 13th, 2009 summary judgment brief that they filed on enablement, we said just that. That was our opposition. But there were these clinical trial results that came through before the patent was issued and we are relying on those. And, in fact, in the deposition testimony, that's what our witnesses talked about. They said: We got those clinical trial results and they were very -- they showed efficacy, and we relied on that.

It really wasn't, your Honor, until after that, when the Federal Circuit's decision on the In re: 318, Appellate Court, Federal Circuit came down with its decision in December of '09 that we had any inkling that this was going to be a different kind of an issue. And, in fact, when they tendered that decision, they, defendants, tendered that to Judge Cavanaugh, Judge Cavanaugh asked for a supplemental briefing on this potential change in the law or different way of looking at the law. And we responded promptly with our contention that

not only could we re -- not only could we prove that the patent was enabled by the test results that the Mass General study had generated, but there were other things that had been fully disclosed during discovery that we could rely on, such as the fact that Mass General went ahead in the first instance with this test and filed for FDA approval, or FDA permission to go forward with this Phase II test. The fact that the FDA in fact did permit the Mass General folks to go forward in a Phase II clinical trial of the drug for ADHD. The fact that Lilly wanted to give them the drug and to promote it for that purpose. All of these were actually set out in our November, 2009 opposition brief where we said: That's part of what shows that if you're not going to take our clinical trial results, for whatever reason, if that's how you took In re: 318, we certainly have all this other evidence that's already in the record. Mass General going forward with it. The fact that they had IRB approval. That's Dr. Spencer in his deposition on behalf of Mass General said that they would not have gone forward without the Institutional Review Board approval. All of that was in our opposition to the summary judgment briefing. Promptly, on the day the Judge ordered it, we discussed all of that and we were relying on what was already in the record. These are deposition testimony quotes and documents that were in the record.

We got the Judge's opinion in December, that's the

bottom of the third -- what I call the third phase of the timeline. December 31st, 2009, we got the Judge's ruling denying defendant's motion to -- for summary judgment on enablement. And there were things in that amended opinion that caused us concern because there was this issue that we thought we could rely on, the Mass General clinical, and still believe we should be relying on the Mass General clinical trial results. That just because the patent examiner didn't happen to ask us about that, because he, the patent examiner, didn't question the enablement utility issue, we should still be able to tell the Court that's good grounds to hold the patent is valid like, you know, like an issue out of the patent office. So we said: We'd like you to reconsider on that point.

It wasn't until we lost that point before the Judge, and he ruled on his -- on our motion for reconsideration on February 23rd, that it really even became an issue for us as to identify a witness who could address all of these. Okay. If we can't talk about just relying on the clinical trial results, let's -- who's our witness that can talk about Lilly's business and the whole purpose of Phase II trials, and how they're conducted, and what goes into them, and all of the things that Dr. Watanabe had -- would have been our witness for? I mean, we searched for who that would be. It would be Dr. Watanabe who would fill that role. He clearly testified at his deposition about all of the ways in which Lilly goes about

engaging in the drug discovery process, including what's involved in Phase I, Phase II, Phase III. He talked about his knowledge of the Mass General test. The results. All of that. He would have been our witness, but he was -- he unexpectedly had died. So we cast about for who was an alternate witness, and mid-March we got our first preliminary meeting with Dr. Paul. And he was in the process of retiring and shifting after many years with Lilly, as President of Lilly Research Laboratories.

We had a second meeting scheduled on April 5th, the day the witness lists were due to be exchanged. We were in Indianapolis to meet with him. He cancelled at the last minute, he had a family emergency, his mother-in-law had a heart attack and was in the hospital. So we didn't actually get to meet with him. We identified with him right away then any way as the person who could fill Dr. Watanabe's shoes and testify to what is involved in the drug development process.

What is involved in these ethical guidelines that govern both the business that we're in and that the defendants are in? The kinds of requirements that are -- that were fully identified in not only our documents, your Honor, but their documents as well, defendants' documents as well? And to suggest that we didn't actually disclose this in discovery is just not wrong -- it's just wrong. It's not true.

For example, on page 2 of the next slide, we have a --

we have the fact that we did provide a witness to testify on these topics. They complained we didn't have a 30(b)(6) witness on Lilly's knowledge of the involvement of Lilly in the Mass General study. We did. That was topic number one of their 30(b)(6).

We gave a witness on the history of atomoxetine from its first synthesis to the filing of the patent, and all about the human clinical testing about atomoxetine. That's what we offered to provide, and that was done in full compliance with our -- their request for a 30(b)(6).

We also, your Honor, gave them on the next page in response to another 30(b)(6) request, a witness to testify on Lilly's knowledge of its involvement with the MGH study. And we said we would give them -- that was a very broad request, and we gave them someone who could talk about general research and development of Strattera. Again, they had another broad request, which is the next question, your Honor. Investigator-initiated trials. We gave them a 30(b)(6) on that.

And on the next slide, your Honor, they asked for all agreements with and any and all fees paid to Drs. Biederman, Spencer, Wilens, all the folks at Mass General. And we gave them a witness on that. The only thing we didn't do that they have raised in the context of a 30(b)(6) is we didn't have a witness who could testify about Mass General's preparation and

filing of its IND, which was a very narrow, narrow request. And that's the only thing we didn't do. But they did have, during discovery, your Honor, several witnesses who talked about the IND process and Lilly's knowledge of the Mass General study.

And that is, for example, on the next page they asked Dr. Hynes: Do you have an understanding that the Beiderman trial, the drug product came from Lilly? And he answered: Yes, sir, it's my understanding that we provided clinical trial material to Dr. Beiderman.

So in sum and substance, in this whole discovery process, well before we even got their non-enablement contention, we put forward witnesses who were very open about what they knew about the Mass General study and what Lilly had done.

Again, they asked, on the next page: So you have knowledge that Lilly provided material for the study, and you have the knowledge that Lilly provided some funding for the study? Dr. Hynes answered: That's correct. And, again, they asked our 30(b)(6) witness Dr. Hynes: Do you know what an investigational new drug application is? Yes, sir, I do. What is that? Answer: It's basically going to the FDA to get permission to begin clinical trials on an investigational new drug.

THE COURT: Could I interrupt for one second and just

ask a question of you --

MS. MASUROVSKY: Yes, Judge.

THE COURT: -- Miss Masurovsky? I must say that, you know, all of the things that you're saying are -- were not included in your briefing, so I'm hearing this stuff for the first time right now. This is all new to me, which is fine. But I want you to understand that. But if you, for example, I look at page 21 of what you've given me -- I don't know which slide it is, but Lilly designated witnesses to testify on topics that include Lilly's knowledge of and involvement in the MGH study number 3. So who was that witness?

MS. MASUROVSKY: Your Honor, just for clarity of the record, these arguments are actually captured in our opposition to their other motion In Limine on the -- on the documents and the IND, the Mass General IND. So I just -- these are my notes for this particular set of points that I wanted to make, but it is also in our briefing. I can probably give you the docket entry number in just a moment. I don't have it.

THE COURT: I think I'm familiar with it, although, I mean -- I don't think it's a motion that, you know -- it's a different motion. And I don't think that I'm handling that one for a variety of reasons. So it's really not criticism, it's just -- it's all new. This is very new stuff for me here. Obviously there were many In Limine motions and hundreds and hundreds of pages, so I may have read part of that motion, but

I didn't see this.

In any event, who was the witness that testified about this?

MS. MASUROVSKY: The 30(b)(6) witness who testified about this particular topic was Dr. Hynes. And I only used it to illustrate that there's nothing new in what Dr. Paul is going to testify about. There are no surprises in what Dr. Paul's anticipated testimony is. It was all fully vetted in many, many, many deposition questions; many, many, many documents. And so when I take the Court through what Dr. Paul is anticipated to testify to that we would have asked Dr. Watanabe, I just want to put it in this context of, there's nothing new under the sun here. These are topics that Dr. Watanabe addressed in response to questions, our 30(b)(6) witnesses addressed in response to questions. I really just wanted to put what Dr. Paul will say in the context --

THE COURT: And I'm going to let you finish. But what's the problem with having Dr. Hynes testify to this, as opposed to -- why do we need a new witness, Dr. Paul?

MS. MASUROVSKY: Well, again, it's not in our view a new witness, it would be the same as Dr. Watanabe's perspective.

THE COURT: That doesn't really make sense on a certain level because, I mean, you yourself said that -- I mean, first of all, the description of Dr. Watanabe was quite

limited. It was just some information about the development of the drug, basically, of Strattera. And that you, yourself, have conceded that when Dr. Watanabe was identified and probably deposed, this was prior to what you basically described as a sea change in the law of Janssen. And so we are dealing with a new issue. So I'll get to that later. But I just -- I want to go back to my question. If indeed you did respond to this 30(b)(6), which does seem to overlap somewhat with the information in the proffer, why not Dr. Hynes? Why do we need a witness designated for the first time on April 5th, Dr. Paul?

MS. MASUROVSKY: Well, with all due respect to Dr. Hynes, Dr. Watanabe's perspective as the President of Lilly Research Laboratories, and Dr. Paul's perspective from that, and his background, having been in charge of drug development for many years, and his specific clinical expertise. They both were at the National Institute of Mental Health. They both brought to the position of drug development a certain particular expertise and perspective from the top and from the bottom up, and from both being MDs, clinical investigators, themselves. Dr. Paul will testify about what it takes to get to a Phase II trial. And having sat on an Institutional Review Board, he brings to the perspective -- he'll bring to the Court the perspective of what a drug development company must go through to get through these various stages from that

perspective. He brings to bear particular experience. And they both have markedly, Dr. Watanabe and Dr. Paul, we feel very fortunate, they had very similar training and experience and roles in Lilly's drug development process and in their prior experience. Again, both are MDs, both were at the National Institute of Mental Health. Dr. Paul knew many of the researchers in the ADHD field, as did Dr. Watanabe. Dr. Watanabe had worked in catecholamines at NIMH, and that's also Dr. Paul's strong suit where he came from, NIMH. So they both brought to bear the experience outside of industry and in practice, and the knowledge of the drug development process unique to that aspect of it.

THE COURT: Okay, go ahead.

MS. MASUROVSKY: I'm sorry. And that is the perspective that we think is fair and important for this Court to hear in deciding this ultimate legal conclusion of whether or not the patent meets the criteria of Section 112.

THE COURT: What --

MS. MASUROVSKY: With all due respect to Dr. Hynes, he's a very knowledgeable, good person. But it's a different perspective that Dr. Watanabe brings to bear, or Dr. Paul brings to bear. And, in fact, at Dr. Watanabe's deposition, rereading it, it's clear the defendants knew where they were going. Now, looking back on it, we didn't have the benefit of their contentions, but they asked a lot of questions that bear

directly on this enablement question about what he thought before he got the clinical trial results, what he thought after he got the clinical trial results. So there is actually a lot of testimony which now we understand in hindsight, since they've revealed what their position is, that they were asking about this particular issue. And it is a perspective that we think is unique and vital to the Court's appreciation of how to resolve this issue.

THE COURT: Well, perhaps you can take me through that. I mean, it seems to me, and of course I have a lot of issues about the Hynes versus Paul issue, what you just said. Presumably you're saying Dr. Paul is going to give different testimony than Dr. Hynes did on the development and research of the invention.

MS. MASUROVSKY: He's going to bring a particular expertise and, I mean, a particular perspective as a fact witness --

THE COURT: Which no one has heard so far. It's brand new.

MS. MASUROVSKY: It is what Dr. Watanabe would have said. Again, it's not brand new in the sense of -- it's not a brand new issue. It is not testimony that anyone has heard in the sense of we did not take his trial testimony. We did not take Dr. Watanabe's trial testimony, direct testimony, at his deposition. We had no reason to believe he would not be here

for the trial.

As I mentioned on the phone, it was very unexpected. He committed suicide after his daughter died unexpectedly from a routine medical procedure. There was no reason he would not be here today on the trial witness list. And frankly, your Honor, defendants would be only able to object to questions as we posed them to Judge Cavanaugh if Dr. Watanabe were still alive. Dr. Watanabe would be testifying. He was deposed. He was a fact witness. He could be a fact witness. They should not be able to profit from his untimely death. And that is what they're asking the Court to do.

You know, in most cases when a witness dies, the Court rules that a substitute maybe heard because that person may have important information. And we believe in this case, vital to the resolution of a core issue in the case. And the way to deal with that, because prejudice from excluding that evidence is so great, the way to deal with that is to take a deposition, the same as you did with that other fact witness, so that they're on equal footing.

THE COURT: See, he tragically died 10 months ago. So you had a little time difference here. We're on the eve of trial, but I understand your point.

MS. MASUROVSKY: But the reason we didn't know we needed him 10 months ago is because the Federal Circuit decision on 318 hadn't come down until September. And more

importantly, Judge Cavanaugh's ruling on our motion for reconsideration, which provoked the need for Dr. Watanabe, who unfortunately, obviously can not be here, wasn't until February 23rd. And honestly, your Honor, we acted as quickly as we could. We set up a meeting for March to see if we could find a replacement witness in Dr. Paul. I honestly could not have gotten to speak with him before that. We tried. We acted with all deliberate speed. We would not have Dr. Watanabe as an issue at trial but for the Judge's decision on reconsideration. We would not need him.

THE COURT: I'm not -- well, I mean, on reconsideration, of course you had the summary judgment decision.

MS. MASUROVSKY: Okay.

THE COURT: You had the Janssen case that came down a month or two before. I mean, there were many earlier points in which a witness could have been identified. I'm not saying that it's dispositive of the issue. But even if Dr. Watanabe -- I mean, had a very general description of knowledge, and I'm not so sure that the defendants would not be objecting were he available right now because, just by your argument and by your concession, the subjects that he seems to be, or that you seem to want Dr. Paul to testify to, are new subjects. But, you know, in other words, in the supplemental disclosures, Lilly identified Dr. Watanabe as a person with

knowledge regarding certain aspects of the development of Strattera. And then in your disclosure, Dr. Paul, he's identified, one of seven witnesses, which raises another question, that may "address the invention in suit. Its background and development. A claim long felt but unmet need for this invention, and how the invention was made and used." That's the way he was described, Dr. Paul, on April 5th. Which really brings me back to where I started, and I am going to let you continue with your presentation, but I would think it would be helpful if you, and maybe it's part of your presentation, would explain what Dr. Paul's testimony would go to. In other words, it seems clear, we now know, despite I guess disagreements, but it seems clear that the fact of the Mass General testing and the Institutional Review Board, et cetera, is all out there, part of the record, well known to both sides. It was considered in the summary judgment opinion. And arguably based on -- not arguably, but based on Janssen, Judge Cavanaugh decided that the failure to provide the testing results to the Patent Trademark Office raises a serious question about the validity of the patent.

So what is it that Dr. Paul is going to say -- is it the thought that -- I really need to hear. Is it that you're going to try to use this kind of rational analysis theory of Dr. Paul to try to fit in the narrow window that would seem to be discussed in Judge Cavanaugh's opinion, or is it that he

simply is going to explain that there was this testing out there, and even though it wasn't supplied -- I'm not sure what -- I'm not sure really where he's going or where you're going with his testimony. If you could clear that up, I think it might help us.

MS. MASUROVSKY: Let me take a stab at that then.

THE COURT: Okay.

MS. MASUROVSKY: I think what we would anticipate Dr. Paul explaining to the Court is, if I may, by way of analogy.

THE COURT: Sure.

MS. MASUROVSKY: Would be like in a case, let's say an SEC case where there was an allegation of a prospectus that was misleading. And it would make no sense to have the prospectus in evidence, but not have a witness be able to explain the business in which the prospectus was written so that the Court could determine whether or not the statement was in fact misleading or whether or not it was material.

So Dr. Watanabe would have filled the role. And he did in his deposition. I'd just like to read a few excerpts, explain what the business of being in the business of drug development is in, which is the business the defendants are in too. I mean, their documents are filled with these -- the references to the Helsinki Declaration, and all these other requirement -- these underlying, underpinnings of the rules, the regulatory framework in which human clinical testing is

conducted. So this is not new, but, for instance, Dr. Watanabe, in two different places in the deposition, I'm just going to read from one --

THE COURT: Okay.

MS. MASUROVSKY: -- as an example. From his October, 2008 deposition, page 154, line 16, says: Well, there are -- the development of the drug takes 12 to 15 years. And as I reviewed earlier, there are multiple phases. Phase I takes about a year. Phase II takes two to three years. Phase III takes three to five years. At each of those points going into Phase I, going into Phase II, et cetera, it's a major milestone and there's very in-depth review of all the data of safety, efficacy and so forth.

And so in part what we want Dr. Paul to do is to talk about the process by which Lilly undertakes to decide to go forward in Phase II trial. What is the process that an Institutional Review Board, having sat on an Institutional Review Board, he knows what's involved from personal experience of the criteria for going forward with a clinical trial. And he would talk about his specific experience.

If I may turn to his anticipated testimony in the offer of proof, your Honor.

THE COURT: Sure.

MS. MASUROVSKY: So in the background he would talk about his having been in charge of the therapeutic area at

Lilly that was responsible for discovery research, including Phase I and Phase II medical research that covered the, as he was identified by Dr. Watanabe in his deposition, in charge of the central nervous system drug development.

THE COURT: Can I stop right there?

MS. MASUROVSKY: Sure.

THE COURT: Defendants, why is that a problem right there, if that's all he was going to say, the fact it's, this is the way it worked?

MR. CLEMENT: Well, I think that most of that is actually covered in the Watanabe deposition designations. I mean, it's duplicative. It's cumulative. I don't think that these facts in the background were -- you know, I have a whole chart that I'd like to go through with your Honor breaking these down, but I think, you know, if Dr. Paul --

THE COURT: I was just looking for a simple answer. In other words, breaking it down, I can see where further testimony would be objectionable, but that testimony, one, seems to have been dealt with by Watanabe.

MR. CLEMENT: Exactly.

THE COURT: And two, I mean, so perhaps it's duplicative, but it doesn't seem like a lot of prejudice to have Dr. Paul testify to it.

MR. CLEMENT: If it was limited to that, we probably wouldn't be here.

THE COURT: You see, I'm trying to figure out what they're going to be limited to. Thank you. Let me let Miss Masurovsky continue.

Go ahead.

MS. MASUROVSKY: Thank you, your Honor.

Again, it is our position and our request that we not of course be limited to only what Dr. Watanabe said in his deposition because we did not take his direct trial examination. Again, if he were alive today, the things that we would ask him at trial would not track what my adversary asked him and the answers they got.

THE COURT: Understood.

MS. MASUROVSKY: It was honestly a completely legitimate call, one that's made every day of the week, unless someone is sick, not to have all your trial testimony come out in the deposition. And so we would not, if Dr. Watanabe were alive today, we wouldn't be limited by anything other than what Judge Cavanaugh ruled was an objectionable question at trial. And to force us into the box then again it's punishing Lilly and frankly the search for the truth by the Court that Dr. Watanabe committed suicide. And that's not the way the Federal Rules of Civil Procedure are suppose to work.

THE COURT: That's true. The defendants take the position that he was five years retired from Lilly, and his availability is a question mark. And that the plaintiffs took

a gamble by not questioning him. That's one thing, I think, that they're saying.

And then I guess what I also might add, even though I, on the ultimate issue, I tend to agree with you, plaintiff, on that. In other words, I find it hard to punish or blame under the circumstances the plaintiff for not taking the deposition of Watanabe at that point. But I think that you took another gamble, the plaintiffs did here, in the context of the -- of what would happen with the law and with Janssen and the reconsideration. And I think there was another gamble there.

But, go on, I understand that.

MS. MASUROVSKY: So our position is that based on his background, which is set forth on page 1, where he served as Scientific Director of the Intermural Research Program on Institutional Review Boards for the National Institute of Mental Health where, by the way, Dr. Watanabe also worked after medical school, he could and would talk about his background and experience. And in particular, on page 2, as a member of Lilly's Executive Management, the head of a multi-billion dollar Research Development Organization, he will identify the steps Lilly undertakes to bring to fruition a new treatment for a disease, including those Lilly took to develop atomoxetine for the treatment of ADHD for children and adults, and for its maintenance indication. And most importantly, he'll describe the steps that Lilly takes when it believes a chemical compound

is useful in treating a particular disease. And we'll walk the Court through what the meaning of those steps are and what it means to file an IND. And most importantly, that Phase I is a step in the process that involves perfectly healthy people and it's done to establish safety.

But then the next phase is that if it's not toxic and it can be useful, considered useful in treating a disorder, it moves into Phase II, and that these are tests done if patients having a particular disorder and a rationale is applied when that happens, when that transition is made. And Lilly does this kind of review every day of the week. That's part of the process. And it was done here when Lilly allowed Dr. Heiligenstein to offer clinical trial bottles, vials of pills, capsules of atomoxetine to Mass General and then allowed Mass General to file an IND that cross referenced Lilly's IND. All of those things happened in this case. And the significance of what that means, which is critical to the Court's determination given where we are on this issue of whether people of skill in the art at the time could believe and did believe that Strattera could be useful in treating this disorder.

THE COURT: Sounds a lot like expert testimony, at least the last part of that. You know, certainly what happened, I think it's sort of a matter of record here. I think Judge Cavanaugh knows it, and I can't imagine that it be given that there seemed to be some new 30(b)(6) notices that

would seem to have been responded to about what happened, the steps, et cetera. That's fine. You start describing the significance and how it might impact upon enablement, utility, that's expert testimony, isn't it?

MS. MASUROVSKY: Your Honor, I was actually pointing to what we would argue, but not what Dr. Paul will say. We will only talk about what he knows from his personal knowledge, as would Dr. Watanabe. I'm saying we, the lawyers, should be free to argue whatever inferences, and they can argue if it's immaterial or irrelevant through cross examinations. They can object. They can expose, if they believe there are weaknesses in that personal testimony, and argue what they want. I was making -- connecting the dots for why it's important. I was trying to put his factual personal testimony in context. And respectfully, your Honor, it's very different having a live witness than having a cold deposition in the record. And, again, we did not ask Watanabe all the drawn out, clarifying questions that we would ask him at trial. And that is what we are in a position to lose and be prejudiced by, should the Court not allow us to go forward with his replacement who would say in his stead what he would say about the significance to Lilly and what the meaning to Lilly of these steps in the process.

THE COURT: And why is that relevant to the issue?

MS. MASUROVSKY: Because the Judge will be taking into

consideration what people in the field did at the time. And looking at what people in the field, the state of the art of people in the field actually doing the work thought at the time. And that is what's relevant to the inquiry, given the way the case is shaping -- shaken out.

THE COURT: And the plaintiff doesn't have an expert on that issue?

MS. MASUROVSKY: We don't -- it's not for expert testimony, it's for what people actually did. What we want Dr. Watanabe -- rather, Dr. Paul, at this point to testify to, is what Lilly actually did, what Lilly actually believed, what Lilly's business was all about.

THE COURT: What Lilly believed. In other words, their state of mind is somehow relevant to this issue? I'm not going to decide any of these evidentiary issues one way or another, but I'm trying to understand it.

MS. MASUROVSKY: Not their subjective state of mind, but what their actions and what provoked their actions. What they were considered. What considerations Lilly -- was relevant to Lilly as a drug developer. I think that is highly probative and highly relevant of the issue of whether other persons of skill in the art, including Lilly, reading the disclosure in the patent, would have believed it to be a credible statement, a credible position of utility.

THE COURT: Pure expert testimony, seems to me, but go

ahead.

MS. MASUROVSKY: Again, we're trying to show through factual testimony what people on the ground really did. And we think that can be taken into consideration as much as any expert opinions, and sometimes could be more probative than an expert opinion because it's the true state of the art of what people doing at the time thought, did, believed. And defendants actually questioned Dr. Watanabe at length about what he thought, believed, et cetera, on this very topic.

THE COURT: Which I can't -- well, I don't know about what he thought or believed about what happened, the facts, I can't imagine being a problem. I think that, one, they're already out there; two, presumably you provided that in answer to the 30(b)(6), and presumably you responded to interrogatories with that. I don't know if that's true, we'll hear from the defendants later. I don't know whether those contention interrogatory -- once again, this goes a little beyond what I'm faced to decide. But whether there was a contention interrogatory in which this theory, this somewhat new theory was responded to, I don't know.

MS. MASUROVSKY: Again, your Honor, if I may refer you back to the timeline.

THE COURT: Okay, let's go back to the timeline.

MS. MASUROVSKY: Page 1. This theory was, of non-enablement, was only disclosed to Lilly after the close of

fact discovery, after Dr. Watanabe was deposed, after all the depositions, including Lilly's 30(b)(6) depositions were done. And our answer that we looked at, our answer after we got their supplemental interrogatory response, which was in November, 2008, we looked at what we had answered and it remained true. It remained true that we didn't have anything different to offer at that time. We believed that we could stand, as a matter of law, and I believe this was -- we continued to believe this is correct on the clinical trial results of Mass General Hospital. It was only after the Janssen case in the fall of 2009, and the Court's interpretation of that in the end of 2009, and early 2010, February, 2010 on motion for reconsideration, that it became a different question for us in terms of what we were going to focus on. And our contentions were not in our answers to interrogatories, but they were spelled out in our -- and I have a few slides on this in our opposition briefing, supplemental opposition that the Court requested.

So if I may just continue --

THE COURT: Continue.

MS. MASUROVSKY: -- on what Dr. Paul would cover. From his personal knowledge, he would say that it was well known to him and to Dr. Watanabe, who he met with on a weekly or at least monthly basis on these issues, that at the top of page 4, that as managers of human clinical research, both he

and Dr. Watanabe were aware in the mid-1990s, the relevant time period which the Court will be judging the patent in suit, that experimental drug should not be administered to a patient in a Phase II study unless there is an objective and reasonable belief the drug will be effective to treat the target disease, and those benefits to the patients outweigh the risks.

THE COURT: Sound like expert testimony to me, but go ahead, that's his opinion, presumably. It's an inarguable fact.

MS. MASUROVSKY: It is an inarguable fact from Lilly's business perspective. This is the business in which Lilly is in. This is how he and Dr. Watanabe, as managers of the clinical research, conducted their business. It's objectively proven, your Honor, in the documents that defendants have produced and the documents that Lilly produced in the clinical trial agreements that Lilly signed with Mass General. Each clinical investigator must swear that he or she will abide by these ethical principles. They are spelled out in documents. They are in their abbreviated new drug application documents. They require their clinical investigators to sign on the same dotted line that they will abide by the Helsinki, the principles set forth in the Helsinki Declaration. These are the guiding principles. It's a highly-regulated business, as I'm sure your Honor knows, and these are the underpinnings of that regulated business, so it is an objective fact. It's not

an expert opinion testimony. These are objectively provable facts through the documents.

And maybe it would help if I turn the Court's attention to one of those documents. If you'll just indulge me a moment I'll find one. It's -- unfortunately it's a little bit out of order, your Honor. But if you could turn to what is maybe the fourth or fifth slide from the end, and it's slide number 6. This was -- the heading is: Compliance with ethical rules and guidelines.

THE COURT: Yes, I see it.

MS. MASUROVSKY: And this is a call out of a Lilly document that the defendants examined on at deposition. And it says: Regulatory considerations. And it's the -- it's from the agreement with Mass General, between Lilly and Mass General Hospital. And it says: This study will be conducted in accordance with the ethical principles stated in the most recent version of the Declaration of Helsinki, or the applicable guidelines on good clinical practice, which ever represents the greater protection of the individual.

THE COURT: And this was discussed or questioned at the Watanabe deposition, or some other deposition?

MS. MASUROVSKY: No, Lilly's -- a different Lilly witness's 30(b)(6) deposition, and defendants asked about this document. I don't think they chose to ask questions about this paragraph, but this was a document that was produced in

discovery and they did ask the witness about the document.

And if you would turn to the next page, there's an example from their own production from defendants' clinical documents from their abbreviated new drug application which is what provoked this lawsuit. Veranda. They too acknowledge compliance with these ethical rules and regulations are the bedrock of conducting human clinical trials. So these are objectionable, provable facts, their very own -- and this is from defendant Aurobindo's ANDA. And when they're talking about giving the version of atomoxetine that they would like to sell to people, would be tested in people, they say they require -- these studies must be conducted in accordance with the provisions of the ethical principles enunciated in the Declaration of Helsinki and the ICH-GCP norms.

And it wasn't just one defendant. If you turn the page, your Honor, respectfully, Apotex also in its ANDA acknowledges compliance with these ethical rules and regulations because their ANDA document says: This research was conducted in compliance with a code of conduct for research involving humans as issued by the Canadian Institutes of Health Research, the U.S. 21 C.F.R. Part 312.20 regulations and the principles of the Declaration of Helsinki.

So with respect -- this is the business that they're in, and we are in. And, in fact, these are such fundamental public documents that are the bedrock of what our business is,

that neither side produced them. And both we and defendants -- and if you'll turn to the next page, they clearly also objected to producing publicly available documents because they were in the public domain.

So we think it's perfectly appropriate to have Dr. Paul testify to what Dr. Watanabe would have testified to on these issues. And it's also important and goes to the core issue of their alleged non-enablement defense for the Court to understand that nobody makes a decision to put a drug into humans who have a disease without believing, having a good-faith basis to believe, and a credible scientific rationale to believe that the drug could be effective. And that's an important guide post for this Court to have in making and rendering its decision on the validity of this patent.

Dr. Paul will also testify that he understood ADHD when he joined Lilly because of his experience. Again, like Dr. Watanabe from NIMH, he was knowledge and had worked in this particular area of these kinds of diseases and disorders. He was thus in a position to make informed decisions regarding Lilly's research and develop of atomoxetine for ADHD.

Again, Dr. Watanabe went to great lengths to say why he had heard of Dr. Beiderman from Dr. Paul. And while he, Dr. Watanabe, hadn't done the same kind of research as Dr. Beiderman, he was very well qualified to appreciate whether or not this drug could be effective because he had worked in his

field when he was in NIMH. And so, again, Dr. Paul brings the same perspective that his managers of Human Clinical Research at Lilly, they made an informed decision to go forward with giving Mass General the material to go forward with a Phase II clinical trial.

Lastly, he -- we'll talk about the fact that he knew Dr. Heiligenstein was a passionate child psychiatrist who cared about children and that Dr. -- knew Dr. Heiligenstein to be an insightful drug developer with excellent credibility in drug development before the FDA in the field. I think he was well known to him.

THE COURT: That's opinion testimony there, whatever, apart from the relevance of it.

MS. MASUROVSKY: That would be based on his personal knowledge of those individuals. And like Dr. Watanabe, who knew them personally, again, if we make an objectionable question, that's something Dr. -- Judge Cavanaugh can rule is, you know, is objectionable, inadmissible, whatever. Sustain or object to the -- or overrule the question.

Lastly, Dr. Paul, on page 5, will testify that in 1994, Lilly conducted a Phase II clinical trial of atomoxetine for ADHD at Mass General Hospital under the auspices of Dr. Biederman and Spencer. He will testify regarding the basis for Lilly's approval of this trial as well as its subsequent approval of the Phase III or registration clinical trial, FDA

approval for atomoxetine for ADHD in the United States as well as outside.

And lastly, I think he will bring an important personal perspective, a personal factual perspective, like Dr. Watanabe could have, to the importance of this long felt and need for a non-stimulant alternative to the stimulants that were out there for the treatment until Strattera was approved, which is the first non-stimulant approved.

And, again, if I may just, by way of -- return to a few of these slides, show that we did not, again, keep -- hold back anything that we knew, which is I gather one of their complaints. Again, we gave them everything we could possibly know about what they got from us on their IND process. So, for example, if you turn back to what Dr. Spencer -- the document they had from Dr. Spencer, which is our slide 31, Plaintiff's Exhibit 240, shows that Dr. -- which they had before they took Dr. Heiligenstein's deposition in August of '08, he writes to Dr. Heiligenstein: As we discussed, I'm faxing and then mailing a copy of the preliminary atomoxetine paper, table, figures in comparable figures from adult ADHD methyl phenyl and disapproving studies. In the discussion I outline the argument for the interpretation of, et cetera.

So they, they had the opportunity to ask Dr. Heiligenstein whatever he knew about the involvement with the Mass General study, and they did. And Dr. Heiligenstein told

them at his deposition and provided dosing information and so on and so forth.

THE COURT: But they're not objecting to Dr. Heiligenstein's being a witness at the trial, just about Dr. Paul. No?

MS. MASUROVSKY: I understand --

THE COURT: Okay.

MS. MASUROVSKY: The objection is to Dr. Paul. It's just to show that his role there, we didn't hold anything back. They have accused us of holding something back about what we knew because we didn't offer a witness on Mass General's filing of the IND or preparation of the IND. We said we were not responsible for that preparation, they were. Dr. Spencer answered their questions about how Mass General prepared and filed the IND, and we had nothing to add to that.

THE COURT: All right.

Miss Masurovsky and counsel, I'd like to take about a three- or four-minute recess right now, and we'll come right back.

THE COURT: Thank you.

(Recess)

THE COURT: All right, we're back on the record in Eli Lilly.

Miss Masurovsky, you want to continue?

MS. MASUROVSKY: Yes. Thank you, your Honor.

Let me turn to my final point here. The critical issue here for this Court is what is the prejudice? That's the ultimate question. Excluding evidence is an extreme consequence. Not letting Dr. Paul walk in the door to testify would be highly prejudicial to Lilly and prejudicial to the fact finder, as exclusion of evidence always is. And we ask that the Court apply the rule in In re: Jacoby, where this jurisdiction found, like many others did, that eight of the witnesses of the nine who were identified for the first time on the pretrial order, could testify because they had been in fact identified in either documents or depositions along the way. And the fact of the matter is, the time for identifying trial witnesses was April 5th, when we identified Dr. Paul.

The purpose of having a pretrial order is in fact to choose the trial witnesses that you are going to present at trial, following summary judgment, so that you know what your case for trial is going to be streamlined to be or needs to be. And so there is -- there are these milestones in the development of a case that can't all happen at once, or we would obviously have trials by paper at the very beginning. There is a phase and a process, and we responded to the rulings on summary judgment by determining we needed a witness, we would have called Dr. Watanabe. We scurried to find, as quickly as we could, who his replacement would be and we found, we think, very fortunately, someone who has made himself

available to be deposed, has laid out what his testimony would be so there are no surprises. So that the question of, you know, weighing the prejudice here, the prejudice to us of exclusion of evidence is really extreme, and to the fact finder, but the prejudice to the defendants is to take his deposition. They would be in no worse a position than Dr. Watanabe coming in to testify having taken his deposition. All of the things they are complaining about and finding objectionable, those are within the province of Judge Cavanaugh to decide, as we ask our questions. Are those appropriate questions? Does that call for expert testimony? Is there a foundation for factual testimony on that issue? Those are the normal back and forth things that happen at trial. But whether or not Dr. Paul, like Dr. Watanabe, can walk into the courtroom door and give his evidence to the Judge, we think that's really extreme to Lilly. Particularly where -- and I will now, with the Court's indulgence, turn to my final series of slides, where his role was fully disclosed to the defendants. They knew about as much as we did of him.

And if we could turn to my slide number 35, where Dr. Watanabe identified Dr. Paul as his direct report responsible for neurosciences, very early on in the deposition, it was at page 26, Dr. Watanabe was asked: You don't recall the structure of the Lilly Research Laboratories? And he answered: I do recall that, sure. "Question: Okay. How was it

structured? Okay, Lilly Research Laboratories was structured in different therapeutic areas. Okay. And he goes on to answer: And one of them was neurosciences. And the person responsible for neurosciences reported to me. And defendants asked: And who was that? And Dr. Watanabe answered: That was Steven Paul.

On the next slide 36, he -- Dr. Watanabe talked about his weekly meetings with Dr. Paul. He testified at page 58 of his deposition in October of 2008, I used to meet with Dr. Paul about once a week when we were both in town, since he was one of my direct reports, we'd have maybe a one-hour one-on-one. And he would update me on a number of things, progress in certain projects, issues that were developing. We would talk about them. And I didn't cul it out, but goes on to say: We would talk about science, et cetera, et cetera. So there's no question about what his role was.

In addition, it's spelled out on the next slide in the annual reports produced, all of them, and it showed that when Dr. Watanabe retired from the board, Dr. Paul succeeded him as President of Lilly Research Laboratories, having been his Executive Vice President in that discovery research and clinical investigation role. And that was again a document produced, Plaintiff's Exhibit 774, produced in discovery.

Dr. Paul was mentioned 29 times in Dr. Watanabe's deposition. Not exactly a hidden name. He also was mentioned,

even though I did cul it out in Dr. Spencer's deposition, and Dr. Heiligenstein's deposition, and other people's depositions, so Lilly witnesses and the President of Lilly Research Laboratories made it very clear that Dr. Paul had a prominent, high, important role in this development of this particular drug for ADHD.

Your Honor, the final point here, again, is that the defendants were very aware of Dr. Paul's role as much as we were. It is an extreme sanction to exclude critical evidence and only to be reserved in the -- as set forth in the Meyers vs. Pennypack case, and in the In re: Jacoby case for extreme, extreme circumstances, which are not present here. And if defendants had taken his deposition when we identified him on April 5th, which would have been more than a month before trial, we wouldn't be here discussing this today. That's what we did when we wanted to substitute a witness, we took the deposition. That's again what in most people's practice you do when there's been a death of a witness, fact or expert; often on the eve of trial, sometimes even during trial. Witness becomes available, they have personal problems, whatever it is, most jurisdictions accommodate that, not by excluding the evidence. That's too important and too extreme. But by allowing the other side to prepare, as they would have for the witness during the discovery phase, by taking a deposition.

And, your Honor, with all due respect, we think that

any, any prejudice right now is of their own making because they have chosen not to take Dr. Paul's deposition. There was no reason they couldn't have taken his deposition. And there's no reason they can't take it now. And whatever concerns they have, they can ask whatever they want, get it all out on the table and be as prepared to cross examine and raise there objections to Judge Cavanaugh as they would have with Dr. Watanabe. They'd be in no worse position. And we respectfully ask your Honor not to let them profit from the circumstance we find ourselves in and not to prevent the Judge, the trial Judge from hearing this very important, highly probative evidence. It is a bench trial. Judge Cavanaugh can, of course, decide to rule against us on any particular, and exclude any particular piece of testimony he finds objectionable. The core question for this Court to weigh is what is the prejudice here of excluding Dr. Paul entirely? Should he be allowed to come into court at all? Once he's here to testify, Judge Cavanaugh can rule. If he doesn't like our questions or finds them objectionable as defendants raise objections, that can be addressed at trial. And they will be as prepared for that trial if they take his deposition as they would have with Dr. Watanabe.

So with respect, your Honor, we ask that the Court apply the ruling in In re: Jacoby and allow Dr. Paul to testify in lieu of Dr. Watanabe. Thank you, your Honor.

THE COURT: Thank you, Miss Masurovsky.

Before I hear from defendants, I'm just compelled to make two comments because I think you said that the time for identifying a witness is defined in pretrial. That's really not the case. As you know, if you read the Advisory Committee Notes, and the extensive case law regarding disclosure of witnesses and people with knowledge, the whole concept is early and often, and there's constant requirements to update and keep it current. And frankly I think had the defendants come up with a couple of witnesses that plaintiffs felt they knew nothing about on April 5th, that you might be arguing a different point.

I'd also want to just comment, I think it's important, it's sort of part of a broader issue that's being presented to me. Of course you're right, the narrow issue to be decided is the exclusion or non-exclusion of Dr. Paul, which I will decide. But this all comes in the context of what appears to be a change in the theory or legal position. Once again, no one informed me whether this was covered in contention interrogatories or whether it was updated, but I think to the extent there's risk, I think the plaintiff, by withholding a theory, which I think the plaintiff conceded they essentially did when there's contrary law out there, even if it's just district court law, I think that's a gamble that the plaintiff takes in this case, rather than the defendants. And I don't

know if that's dispositive of the issue, but I think it's important that that be said. So I think at this point, thank you, I'll hear from defendants.

MS. MASUROVSKY: Your Honor, I may have misspoken before. If I may correct something I said before?

THE COURT: Sure.

MS. MASUROVSKY: It was our position that Dr. Paul was made known to the defendants in the course of depositions, and it was our reading of Rule 26 that -- 26E, and the Advisory Committee Notes of the 1993 Amendments, that where the witness was otherwise identified in the deposition, there was no need to supplement. That that forms the basis of letting the other side know that we do not constantly need to be sending new 26A disclosures when the witness has been otherwise identified in the course of discovery. And we, like I said, knew that he had been prominently featured in Dr. Watanabe's deposition, and had been identified in other witnesses' depositions. And so that's what we relied on in our interpretation and understanding of the important Federal Rule of Civil Procedure 26.

THE COURT: That's an accurate statement of what the rule says. I mean, in the context of a complex patent case that's going on for years, where there's been numerous discovery extensions and all kinds of discovery, there maybe a lot of peoples' names who come up in depositions. And so, you're right, that the rule does say that. But there's law out

there that I may address in my decision that in this kind of a case that says that the disclosures have to be very specific and clear, unambiguous, as to the scope of knowledge of the expected testimony.

Once again, I'm not saying that's dispositive of the issue, but there is law that says that.

MS. MASUROVSKY: And also just to clarify my last point.

MR. CLEMENT: I would just like to have an opportunity at some point.

THE COURT: You'll get a chance.

MR. CLEMENT: Thank you.

MS. MASUROVSKY: My final point is it's our position that our legal position was spelled out very clearly, promptly, when we saw their position in their summary judgment briefing in the supplemental briefing in November, 2009, that we rest on that, that that is in fact our position. It was our position then, it is our position now. It was based on only information that was adduced during the discovery process and not anything more than what has been out there or is a well-known public principle of conduct regarding human clinical trials. We didn't go beyond it. We don't intend to go beyond it. And we have, in our view, made our position explicit in that briefing, and there was no possible opportunity for us to do that before, given the way we didn't get their disclosures, and then the law

came out. There was no other earlier place or opportunity for us to address that, given what our interpretation of the facts and the law was.

THE COURT: Today is the first time that I heard that you didn't get their disclosures, one. Two, I understand your position. But given what you just said, the question comes to mind, why did you not then identify Dr. Paul as a witness? Dr. Watanabe had already passed away, had been gone for sometime. So if it was in the early briefing, or in the briefing of the summary judgment motion, one could make an argument that that was the appropriate time to identify Dr. Paul as a person with knowledge.

MS. MASUROVSKY: It was really the end of 2009 that we did that briefing, and we identified him not too much longer after that, in April of 2010. It was not on our radar screen that we needed to choose our witnesses for trial until we saw how the Judge ruled on that issue. Had the Judge ruled in our favor, we would not have needed another witness on that point.

THE COURT: I think, you know, this -- we only have -- we have some of the lawyers who do these patent cases here, and I'm just going to make a gratuitous comment that, a word to the wise, especially in these cases, certainly any case before me, it would be wise to routinely review your discovery responses and update them, especially with persons with knowledge. Persons with knowledge, not necessary -- and especially not

here, given that Dr. Paul was replacement for Dr. Watanabe, there's no reason that he should not have been identified as the person with knowledge, even at the outset. It's not a question of choosing the witness. When the initial disclosures require identification of the people with knowledge that you -- well, in any event, I think there was also some interrogatories that I saw where you were specifically asked about who would be produced at trial. So I think my question is still out there, once again, not necessarily dispositive of the issues, but let's hear from the defendants.

MS. MASUROVSKY: Thank you, your Honor.

MR. CLEMENT: I --

THE COURT: Thank you.

MR. CLEMENT: Thank you, your Honor. I appreciate it.

Your Honor, I think you've hit the nail on the head. What this is really all about is re-litigating the enablement issue. It's not really about Dr. Watanabe's unavailability. They're really -- just like they're re-litigating the In Limine motion. I have to agree with you, everything that Miss Masurovsky just said, was necessarily prepared for because it wasn't in the briefs. They're trying to relitigate the In Limine motions. They're trying to relitigate the enablement issue. Lilly certainly had plenty of opportunities to let defendants know about Dr. Paul and his potential as a witness on the enablement issue, but they chose specifically not to.

And I think the timeline tells that.

I think in our briefing, we've set forth a -- not a graphic as Miss Masurovsky just did, we have a timeline in our briefing that really proves the point. I agree, in November of 2008, at the time agreed, we weren't late in giving our contention interrogatory responses, we agreed to mutually exchange them like two weeks after, or whatever, three weeks after the close of fact discovery. That was when we first put on the record our enablement issue, although we had been asking questions all during discovery about it.

Now, if I were to get a contention interrogatory response with a defense that I had never seen, what would I do? I would certainly update mine to make sure I dealt with the issue. Lilly chose not to. They're saying that this new case, that In re: Janssen, In re: 318, however you want to refer to it, was the reason for it. There was law before that. That's not new law. We cited in our briefs to Judge Cavanaugh, we relied on those cases as well as In re: Janssen. I think there's a Hitzemen case, or In Re: Rasmussen. And there was a Hitzeman case. There were other cases there, your Honor. They went through expert discovery. They didn't put on any defense to it there. We never saw these six documents, the IRB. We never heard from any of these during expert discovery that they were going to reline on that or Dr. Paul. They put in their summary judgment motions. They put in their response to our

summary judgment motion, and they made their own request for reconsideration. Was there a declaration from Dr. Paul? Were these documents there? No, none of that was there, your Honor.

Judge Cavanaugh, I agree, found the defense could proceed and what did Lilly do? They switched counsel. And new counsel comes in and what do they do? That see there's a hole in their case, they want to relitigate their issue, they decide to sandbag us. They took a calculated risk, which they lost. And then they say, okay, we have three months to trial, what do we do? We have to come up with a witness. What is this witness? I think you're right, your Honor, he's an expert witness. Most of what Miss Masurovsky says he's going to testify to is all expert testimony. That really prejudices the defendants because we haven't had a chance to respond to that.

Under Rule 26(a)(2), they're suppose to provide us with an expert report for an expert witness. We're suppose to have a chance to rebut that. We're left with no recourse to rebutting Dr. Paul except for maybe at trial if Judge Cavanaugh allows us to rebut. But it certainly wasn't in their expert reports, not in their summary judgment briefing, not in their requests for reconsideration.

You know, they say that, Miss Masurovsky says that Dr. Watanabe was merely filling -- or Dr. Paul is merely filling the shoes of Dr. Watanabe. But there's no documents that show him as important. Miss Masurovsky showed us a few slides,

deposition topic 1, 3 and 5. That was all covered by Dr. Hynes, who was on their list. So I think that can all be covered there, and they don't need Dr. Paul to do that.

Now, what I'd like to do, your Honor, is I'd like to hand up -- we have gone through our discovery requests and put them in a binder where we think that these are where we should have heard about Dr. Paul or the documents. I'd like to hand that up.

THE COURT: It's a new binder?

MR. CLEMENT: It's a new binder.

THE COURT: Hand it up.

MR. CLEMENT: Sorry. Do you need one as well?

THE CLERK: No.

MR. CLEMENT: And, your Honor, these are all the discovery responses from Lilly to the various defendants' interrogatories -- just excerpts from them, not the entire excerpts. And also, I've also prepared -- and I'd like to make this binder of record on this at this hearing today. These are all Lilly responses, or there is some documents and some deposition transcript.

Also, I'd like to hand up a chart that kind of keys into the --

THE COURT: Can you give Mr. Conlon a copy of the binder, if you have one too?

MR. CLEMENT: Certainly.

THE COURT: It's quite voluminous.

MR. CLEMENT: I apologize.

THE COURT: Okay.

MR. CLEMENT: Sorry.

THE CLERK: Thank you.

MS. MASUROVSKY: Counsel, can I have a copy of the chart too?

MR. CLEMENT: I'm sorry.

Your Honor, what we've done in this chart and in this binder is we've taken the proffer of Paul, and we've given it little A, B -- if you look at the back, you'll see that that shows where the A, B, C and D and everything came from. The proffers are attached to the back. And what we've done is showed where this information should have come in, in our discovery requests, and did not. So I'm going to use that as a guide, your Honor.

But first I want to talk about the proffer, because I think I'm at, a little at a loss, as you are, as to exactly what Dr. Paul is going to testify to. I think at the prior hearing when it was discussed about Lilly making the proffer, at page 26 of that transcript, your Honor stated: The plaintiff might consider a very detailed proffer, including the questions and answers that you would expect to have from Dr. Paul, and as part of your brief. And then at page 27 I ask: Okay. Then maybe they can make the motion first with questions

and answers and we'll reply to that. To which your Honor answered: I think that's a good idea.

The proffer doesn't have the questions and answers, it's just generalized statements as to what he's going to testify to. They don't identify what exhibits he's going to rely on.

Later in his proffer they say he's going to authentic documents. They don't tell us what documents there are, but I'm going to get to that in a minute.

I want to start with -- I want to skip A through -- I want to get to the more important issues first, so I want to go straight through W. Okay?

And W, Dr. Paul they say that he's going to say Dr. Paul's experience operating under the framework of federal regulations and other ethical obligations attendant to human clinical research.

Your Honor, I think that's expert testimony. He's going to explain how the federal, you know, regulations work and ethical obligations. So I think, first, it should be excluded because it's expert testimony.

Second, I think if Dr. Paul had this information, and he's so important to their case, he should have been identified in the 26(a)(1). I think that's an overriding concern. I think we have that listed for every single one of these, that he should have been disclosed in the 26(a)(1) statement. I

think, though, if we also turn to Mylan interrogatory 4.

THE COURT: Where would that be?

MR. CLEMENT: You'll see there's -- in the notebook.

THE COURT: The notebook now?

MR. CLEMENT: Yup, in the notebook.

THE COURT: Okay, Mylan.

MR. CLEMENT: If we go to the interrogatory section. There's a Mylan section under that.

THE COURT: Okay. Which number?

MR. CLEMENT: Four. Four B, specifically. Says that Lilly was suppose to provide an answer as to Phase I, Phase II, Phase III -- Phase III trials, and tell us how each study or trial was conducted, if they were conducted under ethical or, you know, they should have told us that. The response doesn't have any of that information. They say: Refer to the documents.

THE COURT: Let me read this thing.

MR. CLEMENT: Sure.

THE COURT: It's kind of important.

MR. CLEMENT: Absolutely.

THE COURT: Miss Masurovsky, have you read this?

MS. MASUROVSKY: Yes, your Honor.

THE COURT: It seems fairly strong. In other words, they ask the question about these Phase Is, II, III and IV, which presumably, from my reading of the proffer, is something

that you would have Dr. Paul address, and yet when they were asked in interrogatory questions, you got a bunch of objections and never really give them the information.

MS. MASUROVSKY: Your Honor, respectfully, what we did was standard practice in the way both parties have dealt with each other and is common where you have hundreds of thousands of documents, you start by referring to the documents. And that, respectfully, your Honor, is what we did. There are hundreds, and hundreds and hundreds of thousands of documents relating to this issue. And we started by referencing the documents. And we were in fact producing documents, some of which I showed your Honor, which do reference the ethical obligations as set forth in, for example, the regulations and the Helsinki code. And they did use those very documents in deposing witnesses. So they knew about those documents too. As far as I know, they did not make a motion complaining that was not a sufficient way to answer the question.

MR. CLEMENT: Your Honor --

THE COURT: Just let her finish.

MR. CLEMENT: Okay.

Your Honor, typically if you're going to rely on documents, you identify the documents. I mean that's typically how it's done. And Helsinki and all the six documents that are in dispute were never -- they weren't in the production.

THE COURT: I wasn't focusing on the documents.

MR. CLEMENT: Right.

THE COURT: I was focussed on the issue of --

MR. CLEMENT: Right.

THE COURT: There seems to be a clear question of about the Phase I, II, III and trial, and there doesn't seem to be a substantive answer.

MR. CLEMENT: And if Dr. Paul was so important, I would have expected to find it there.

MS. MASUROVSKY: I could be wrong, but I do not believe at the time defendants complained about this being an insufficient answer. I think there were many back and forth, but that was not a complaint we heard from them.

THE COURT: Although, I mean, I'm not -- I agree it would be good if someone has a complaint to bring it to the Court's attention, or bring it to the other side's attention, but I guess they could easily argue they didn't know that it was going to be an issue in the case until now. And then if it was going to be an issue in the case, that the whole theory of the rules is that it be identified. But I understand your point.

MR. CLEMENT: Okay.

THE COURT: I think -- let's let Mr. Clement continue.

MR. CLEMENT: If we look at Aurobindo 9, which I believe might be back a couple sections, which I think your Honor alluded to earlier, it just says: Identify all witnesses

that Lilly intends to call at the trial. And they never updated that either. But that's a blanket one that kind of goes through.

THE COURT: You covered that one in your brief, and you don't need to point to that. If you have more specific ones, I'd be happy to look at it.

MR. CLEMENT: There are more specific ones listed here. I'm going to go through it. I think the Mylan 4B was the best one for this proffer statement. So that's what I'm going to just discuss for W.

For X, although the other ones that we do have listed there do also apply. For X, the approval process a medical institution must undertake to -- for -- prior to commencement of a human clinical trial. I think mostly our big objection to that is it's expert testimony. You know, I think that Dr. Paul should have been identified if he was going to testify to something like that. We do believe -- some of their statements in their proffer are much more general than what our interrogatories were. So this is a more general statement. The interrogatory responses that we identify here are more specific but they would go to the approval process for the atomoxetine product instead of just in general.

If we go to Y, your Honor.

THE COURT: Could I stick an X?

MR. CLEMENT: Sure.

THE COURT: The way it's written there, the approval process a medical institution must undertake prior to commencement of the human clinical trial, I think that's a pretty good shot that's expert testimony.

MR. CLEMENT: Exactly.

THE COURT: But if the question was the approval process that Lilly follows prior to commencement of a human clinical trial, he's the head of the neuroscience unit, that's a fact evidence, isn't it?

MR. CLEMENT: If that was a proffer, I would agree with that. Yes, I agree that would be more factual.

THE COURT: I'm not sure what the proffer is, but go ahead.

MR. CLEMENT: I think that's the problem. If they gave us a question and answer, we might know. For Y, it says: Dr. Paul's testimony will be based on his personal experience as a member of the management team that oversaw Lilly's collaboration with medical institutions on human clinical research trials, his experience as a member of the Institutional Review Board approving such research, and his experience as a physician.

Oh, I want to first, you know, reference this, I think it was the 30(b)(6) topic. It's pretty clear that this, you know, goes to 30(b)(6) topic 18, because what they're really talking about here is Lilly's collaboration with medical

institutions. The medical institution is just a buzz word for MGH, Mass General Hospital, because that's really what's at issue in this case, not any other dealings. And they said that -- and Dr. Spencer testified about the IRB. And they said in their interrogatory -- in their response to the deposition, which we have here, your Honor.

THE COURT: The deposition?

MR. CLEMENT: I'm sorry, the notice of deposition, I apologize, your Honor. But we do have defendants' 30(b)(6) notices and there's really just one in the topic 18, but I think your Honor has seen that already.

THE COURT: Right. But why don't we look at it. Why don't we look at it.

MR. CLEMENT: Okay, that's great. It's in the binder, just a few in. If you can find the dark bolded one that says defendants' 36(b)(6) notices.

THE COURT: Oh, yeah, there it is.

MR. CLEMENT: Okay? And it was -- the topic was the preparation and filing of IND for 46,806, which is the Mass General one. And what do they tell us, they said: Subject to objections, they're aware of the deposition testimony of Dr. Spencer concerning preparation of filing IND 46,808. Although I think that's a typo, it should be 806. And beyond that, doesn't have any responsive information within its possession.

And I think one of the things to focus on here is they

use the word "collaboration" in their proffer. Collaborate -- you know, this is all preparation. They're trying to mince words. One of their defenses or their arguments is, okay, preparation. That didn't mean the IRB and things like that. But when they say collaboration, that's exactly what they mean. So I think that 30(b)(6) statement clearly means they should have disclosed Dr. Paul, or this IRB, or what this proffer is. Instead they chose to just rely on Dr. Spencer's testimony.

THE COURT: But presumably -- I mean, to me, this 30(b)(6) topic, it just illustrates all kinds of problems with the way discovery is being done, and that now on the eve of trial the Court is faced with -- I'll start with the preparation of filing of IND 46,806.

The first line is that Lilly objects to it as not reasonably calculated to lead to the discovery of admissible evidence. Now, arguably Lilly is now trying to use this as evidence at the trial. I guess no one looks back and tries to update these things. I understand, I think it might be a good practice, and I'm not here to lecture anybody, especially such experienced lawyers, to look back and update things, but then it goes onto say. Look, after doing a search, the only information we have about this, the preparation and filing, is by Dr. Spencer.

Now, that's not necessarily a bad answer from my perspective if Dr. Paul or no one else knows anything about the

preparation and filing of IND 46,806. All right, is he going to be offered for this purpose or not?

MR. CLEMENT: It certainly seems to me.

THE COURT: I got to tell you, I'm a little troubled by this too. We had a telephone call the other day, and I read the proffer, and I think plaintiff's counsel said: No, we're not going to talk about 48,606 -- 46,806. And then you were saying, or one of your colleagues was saying: No, Judge, that's what it's really all about. And then I noticed in one of the other briefs that was filed in an In Limine motion yesterday before Judge Cavanaugh relating to the exclusion of all IND evidence, in Lilly's brief is the statement: "The existence of MGH protocol, the IND, which is 46,806, the FDA approval of the IND and existence of MGH IRB approval to do the experiments were all disclosed in discovery. The significance of those events, the alleged non-enablement defense here close directly from the regulatory limitations. The significance of those events, those -- the alleged non-enablement defense here close directly from regulatory tests, regulatory limitations imposed on the conduct of human drug testing. Every professional responsible for drug research is aware of these limitations and requirements. Dr. Watanabe at Lilly, had he lived, could have so testified from personal experience, so can Dr. Paul in his stead.

So now I go to my question, is Dr. Paul going to be

talking about IND 46,806 or not? It sure seems that way from the brief that was filed in the other motion, but I heard the other day that he will not.

MR. CLEMENT: I think he clearly is.

THE COURT: But I want to ask the plaintiff.

MR. CLEMENT: All right. That's fine, your Honor.

THE COURT: Is he going to be testifying about that or not?

MS. MASUROVSKY: He certainly was not going to be testifying, and we have no witness to testify about the preparation of the filing of the IND 46,806. There's no question that no one at Lilly prepared or filed that IND-46,806. That was a very narrow 30(b)(6) topic. I think what Dr. Paul will testify to is not specifically that IND, what Mass General did in its filing of the IND, but to the extent he has knowledge of Lilly's collaboration or working with Mass General in connection with that trial, yes, of course he has factual knowledge about what happened. He would testify just like Dr. Watanabe did. Dr. Watanabe said he first heard of Dr. Beiderman from Dr. Paul. It's not a secret.

MR. CLEMENT: Your Honor, then why isn't he listed? Why did they just say Dr. Spencer in response to -- you know, and Dr. Spencer's deposition was taken. Okay. We spent a day with Dr. Spencer. Lilly then actually cross examined -- he's a third party. They knew he wasn't coming to trial. They

actually questioned him. And they didn't ask any of these questions of Dr. Spencer, and yet they still wanted to just rely on Dr. Spencer. I think they should be, you know, held to that.

THE COURT: Understood. You can proceed.

MR. CLEMENT: Okay, thank you, your Honor.

Also, on that I think the Mylan 4 that we just looked at before, which was, you know, Phase I, Phase II, Phase III, all the -- you know, this is a Phase II study. It seems to be that Dr. Paul's information and all this about the IRB that should have all been disclosed as a result of Mylan 4.

Let me mover onto Z. There we're talking about Dr. Paul will testify that he had -- he and Dr. Watanabe, as managers of human clinical research, were aware in the mid-1990s, and Dr. Paul continues to be aware today, that an experimental drug should not be administered to a patient in a Phase II study unless there is an objective and reasonable belief.

Okay. This is going right to the enablement issue, your Honor. This objective and reasonable belief that the drug will be effective. That's the heart of this non-enablement utility issue. And, your Honor, this is expert testimony. How can a lay person, Dr. Paul, without giving us an expert report, talk about what the objective and reasonable belief was?

Also, I think very highly relevant is contention

supplement 5, if we can turn there. I think that's one of the first ones. It's one of the first couple tabs. Oh, no, that's the supplemental issue. We need the supplemental interrogatory, I'm sorry, your Honor. It's more half way, about half way down. There's a section called supplemental interrogatories.

THE COURT: Okay, I got it.

MR. CLEMENT: Okay.

Number 5, on page 4 there: Lilly's Validity Contentions. Okay? This is Lilly's validity contentions. Then they go and they give a whole bunch, on page 4, they talk about 102 and 103, about the obviousness which isn't really relevant here. But if you get to page 14, I think it is -- I'm sorry, 16, 35 U.S.C. 112. That's where enablement, non-enablement utility comes from, U.S.C. 112. And they did give a little bit of information here on 35 U.S.C. 112 regarding enablement to the full scope. How to make and use the atomoxetine, which is different from the utility issue. There's a couple different prongs to the Section 112 statute. And non-enablement to full scope is another defense that's at issue in this case as is non-enablement utility.

And what does Lilly say at the very end after they talk about some of these patents and things where you know how to make a capsule? They say: Lilly is unaware of any credible evidence establishing a prima facie case that the claims are

not enabled or properly supported. That was the gamble. They said we had nothing credible. Okay.

We've been asking Dr. Heiligenstein: Dr. Heiligenstein, did you have a reasonable belief as to whether this was actually going to work when you put it in a human? He said, 35, 30 times I think we counted, or some number, he said no. He had no reasonable belief. They knew that was on the table. It was case law then, In re: Rasmussen, the Hitzemen case. There's other cases out there. They took the position that there was no credible evidence and they weren't going to have to worry about it. At the same time they filed this, we filed our supplemental contentions, and we laid out or non-enablement utility. Again, they never updated this, your Honor. They took a gamble, they lost. They're trying to come in and relitigate. It's sandbagging. It's like, is that the new way to litigate?

THE COURT: I understand that concept, and I know it's part of the whole consideration, but can you tie that into Dr. Pual for me? I'm still not sure. We read Z, which you said is expert testimony. Sounds like --

MR. CLEMENT: Because what Dr. Paul is saying in Z is that you wouldn't conduct a Phase II study unless there's an objective and reasonable belief that the drug will be effective. If there is a subjective reasonable belief, then there could be enablement utility. And that goes -- that's why

that ties directly in. It's really that portion of this that -- of this testimony that is really objectionable here, and it goes directly to this contention.

THE COURT: What's the context, where --

MR. CLEMENT: The contention was, tell us what your validity contentions are.

THE COURT: Oh, your validity contentions.

MR. CLEMENT: Validity contentions. And then included 35 U.S.C. 112, which includes non-enablement utility in their answer, and they bet the farm. And they should be judicially estopped from re-litigating that now at this late date.

THE COURT: I guess the argument were these supplemental -- what's the date of these things?

MR. CLEMENT: This is November, 2008.

THE COURT: 2008?

MR. CLEMENT: Yeah, before expert discovery, your Honor. There had been plenty of times for them to update this.

THE COURT: When did they get your contentions?

MR. CLEMENT: Same day, November, I think it was 24 --

THE COURT: 2008?

MR. CLEMENT: Yes.

THE COURT: A year before the summary judgment briefing?

MR. CLEMENT: Yes, your Honor. Because then we went into expert discovery, and then we briefed summary judgment.

THE COURT: So these were never updated?

MR. CLEMENT: No.

THE COURT: Okay.

MR. CLEMENT: All right. We also have some others, but I think supplemental 5 is the biggest -- is the best, is the best discovery request we have on point.

If we turn to AA. Your Honor, this is where the six documents come in. Okay? What the proffer that Dr. Paul is going to make is he's going to try to introduce these six documents. And what's it all about? Miss Masurovsky can say it's not about the MGH IND, but right here it says Mass General Hospital's IRB Phase II study. What is that? That's IND 46,606 whatever.

THE COURT: Eight oh six.

MR. CLEMENT: Eight. Thank you, your Honor.

So I think that, you know, we have a lot of document requests which we called for all documents.

If we go to Aurobindo document request 4B. And that should be right after that supplemental -- there should be a section for request for production. Four B is: "All documents relating to any research and/or experimentation conducted in connection with the prosecution of the application of the '590 patent issued," and then it keeps going on. It says: "Or in any way relate to any data, results, experimental or equipment-related conditions, protocols, plans, procedures

concerning the experiments, or studies or tests done by the inventors, Lilly or any other person."

It just seems to me that one's right on point. Talking about the protocols and the tests that were conducted regarding the 590 patent. And that's what Lilly is saying this is all about, this Phase II study, to show the objective reasonable belief that the 590 patent would work.

If we look at document request 75 in Aurobindo. One is: All documents concerning Lilly's decision to file an NDA, which really subsumed the IND, became part of the IND. I maybe wrong, but that's my belief.

If we look at Aurobindo 83, that's one of the catch-all ones: All documents on which Lilly intends to rely upon or use as an exhibit at any hearing or trial. I mean, we ask for these documents over and over. We have a whole list of these. I can go on.

THE COURT: We're onto the documents now, you're not talking about Dr. Paul any more.

MR. CLEMENT: I think in AA, you'll see he's talking about the guiding ethical medical principle is well known in these six documents. This is where these two things converge. You see he has in there the Belmont report, the Ethical Principles, the World -- Helsinki Declaration, the Nuremberg Code. Those are the six documents being referred. They were never produced. We have multiple document requests.

And also, your Honor, because what they want to use these documents for is to rebut our non-enablement utility defense, they should have identified these documents in response to our contention interrogatory 5, which said: Give us your validity contentions. Let us know what your case is. Don't hit us in the last minute right before trial with all this new evidence, you know, we're prejudiced in having to try to deal with.

Also, I think that our 30(b)(6) Topic 18, you know, the preparation of the Mass General Phase II study. Okay. An IRB is something that's part of that preparation and filing process. It's something you have to do in order to file the IND or actually start the experiments for the IND, you need to get approval from the IRB, so it's all interrelated. This is all asked for over and over. They took a risk, they decided not to produce, and now they're trying to come in at the last minute.

THE COURT: Just so we're clear, the issue before me is the exclusion of Dr. Paul as a witness.

MR. CLEMENT: Right. Okay.

THE COURT: I mean, I know you have other In Limine motions out there that may address these.

MR. CLEMENT: We never filed an In Limine motion about those six documents per se.

THE COURT: We'll deal with the six documents, but

other than that, just the whole concept about -- I think that you do have some other In Limine motions out there I saw. I didn't try to read them all.

MR. CLEMENT: Right. Those didn't deal with those six documents, really. Dr. Paul and the six documents seem to converge.

THE COURT: Okay.

MR. CLEMENT: At this point, AA and his proffer.

AB. Okay, Dr. Paul will testify that he had a substantial appreciation for ADHD when he joined Lilly. We don't have that much -- you know, it seems what is substantial appreciation. He could be speaking as an expert clinician, but, you know, I don't think that that's a huge deal, although we do think that we asked for Dr. Paul's identification in many interrogatories, and he should have been identified to us.

If we move onto AC. Now, here's one. When he joined Lilly and assumed responsibility for the development of atomoxetine for ADHD, Dr. Paul understood that it is a chronic and complex disorder for which the existing FDA-approved treatments carry significant liabilities, such as abuse liability.

Okay, why do they want to enter that? It doesn't have to do with non-enablement utility. This one goes to a secondary COURSE, long-felt need?

We asked about long-felt need. If we can go back to

that contention response 5.

THE COURT: Which one, contention response.

MR. CLEMENT: Supplemental interrogatory number 5.

THE COURT: All right.

MR. CLEMENT: And if we go to page 12. They have a section here on long-felt or unmet need or failure of others. I don't see anywhere in there about Dr. Paul. I see a little bit in there about some case law. They talk about Heiligenstein deposition; a Burton TS, I'm not sure what that is; a couple prior art references. We turn the page, you know, they have a few other references, then they talk about a couple of deposition transcripts. They have Allen mentioned, two pages from Watanabe. They have Heiligenstein, they have Allen again, nothing about Dr. Paul. Never updated. This is the last word, and what they were going to use for long-felt need. They put an expert report on that. Dr. Paul's never mentioned, you know.

THE COURT: So that there's expert reports on it, what does it matter that Dr. Paul understood something about the disorder? I don't understand why that's even a concern.

MR. CLEMENT: I think it's been unfair. Yes, they're going to have an expert. It's cumulative. Why do they need Dr. Paul? They have their expert on it. Why do they need Dr. Paul?

THE COURT: I know, it sounds more like an evidentiary

type of issue.

MR. CLEMENT: Okay.

THE COURT: I don't see that -- I mean, if they have an expert report on the subject, the fact that the company or the head of the science department felt the same thing, that's not --

MR. CLEMENT: Your Honor, we could live with him testifying on that. We think it's improper, it's expert testimony, we should have had it. Okay. I mean, we could live with that.

AD. Dr. Paul was thus in a position to make informed decisions. And here I think, you know, it's just talking about Dr. Paul talking about the composition of the management committees. Okay. Again, we're getting surprised here on this one. We asked Lilly in Apotex interrogatory number 2, to please identify every individual or entity, right, who contributed to the conception. If you go down to the last two sentences: Please identify all supervisors of the named inventors of the patent-in-suit at the time of conception of reduction of practice.

They're saying Dr. Paul was that. But he's not mentioned in their answer. All they mention here is Heiligenstein and Tollefson, two inventors, and they have this blanket reference to: Look at all our documents.

So, again, while this testimony isn't so critical, I

don't think, to the case, again it's another example where they should have given us the information. They didn't. As counsel pointed to the extent they want to use that testimony for showing utility that maybe in his management committees, which we don't have the minutes of, Dr. Paul is going to say that they, you know, decided that there was utility for this to go ahead. I guess we would object to that. But just the fact as to what a management committee is, I think that's -- I think Dr. Watanabe actually testified to that at page 82 of his deposition too. I think we have that over there on the right. Actually, I think what Dr. Watanabe testified to it on page 82. And DTX 118, if you take a look at DTX 118, which is in the very back, and this is an e-mail from Dr. Watanabe to Drs. Heiligenstein, Potter, and Tollefson. Dr. Paul is cc'd on it. And he says: John, Bill and Gary. Heiligenstein, Potter and Tollefson. And he congratulates them on the success that they had. And when he was asked: Why did you congratulate Potter? On page 82 of his deposition, which we also have in here. "And so I just basically wanted to congratulate the three key players who carried it to that point." This is on page -- this is what he's referring to, that document. He wanted to -- he sent that e-mail to congratulate the three key players. The three key players are Heiligenstein, Potter and Tollefson, not Paul. Again, why should -- just because Paul is cc'd on that e-mail, it gives us no clue as to having to depose him or why

he's here as a surprise witness.

If we move onto AE. Dr. Paul will testify that he knew Dr. Heiligenstein to be a passionate and devoted psychiatrist. I don't know, that's lay -- that's opinion. You know, I don't know -- I don't even know what to do with that, your Honor.

On AF, though, your Honor, I have a bigger problem with. You know, here they're saying Dr. Paul knew Dr. Tollefson to be an insightful drug developer and scientist with excellent credibility before the FDA regarding the merits of the drug. This is code for enablement utility. Credibility before the FDA regarding the merits of the drug. You wouldn't put -- they're going to say you wouldn't put something in unless you knew it was going to work.

Now, why is that objectionable? If you look at the stipulation, your Honor, Dr. Tollefson passed away, and we were trying to depose him. And instead of deposing him, we entered into a stipulation. It should be at the end, I'm being told: DTX 43, at the end. This is a stipulation, your Honor, signed actually back in October of 2008. And, you know, there actually was a big dispute about this, and we settled. We settled the matter. And number 2 says: "Neither party shall be advantaged nor disadvantaged by the absence of testimony from Dr. Tollefson." They're trying to get an advantage about Dr. Tollefson through Dr. Paul. I really think that should

come out. They stipulated they wouldn't rely on those things. We did not take the deposition, now they're trying to back door.

Okay. We move onto AG. Dr. Paul will testify that in 1994, Lilly conducted a Phase II clinical trial. You know, I find this one a little hard to understand. Dr. Paul will testify that in 1994, Lilly conducted a Phase II clinical trial. I thought MGH conducted the study in 1994. I'm not even sure, you know. And Dr. Watanabe, who they're saying Dr. Paul is going to be put in, he actually contradicts that at pages 32 to 34 of his deposition. It was MGH, Lilly didn't conduct it.

THE COURT: It must a typo, no? Is that a typo, AG? In other words, they're talking from the proffer, because I remember in reading it, it was MGH and those doctors doing the clinical trials. Lilly didn't do it, did they? Or did they? I don't know.

MS. MASUROVSKY: Your Honor, may I respond?

THE COURT: Yes.

MS. MASUROVSKY: Mass General Hospital, through Drs. Beiderman and Spencer, actually conducted the trial. But it was Lilly's clinical trial material that they had. It was provided by Lilly. And it was Lilly's IND that they were able to use to go get the FDA to allow them to put it into humans. So Lilly provided all the pre-clinical work that the Mass

General Hospital referenced in its IND.

And we testified at great length about that on the various depositions that -- and Dr. Spencer from Mass General also testified that Lilly permitted him in his IND-46,806 to cross reference Lilly's IND. Again, the way all this works would be something that Dr. Watanabe could have explained, but, again, we would like to offer Dr. Paul to explain how all this works. But, again, Dr. Spencer's IND-46,806 referenced -- cross referenced Lilly's IND, and it was Lilly's clinical trial material that was used in the Phase II trial conducted by Drs. Beiderman and Spencer at Mass General Hospital.

THE COURT: Okay. Thank you.

MS. MASUROVSKY: And also Lilly contributed funds. Lilly paid --

MR. CLEMENT: Lilly did not conduct --

MS. MASUROVSKY: -- a portion of the study.

MR. CLEMENT: Your Honor, it's getting -- twenty to one. What -- would you like me to continue?

THE COURT: Only on that one. Did you cover that one? Where did you ask for stuff that would have given --

MR. CLEMENT: Mylan number 4, that was the one -- remember we went through that? Give us all your information on Phase I, Phase II, Phase III studies.

THE COURT: Oh, yeah.

MR. CLEMENT: And also deposition topic 18. Thank

you, Tom. So if it related to MGH study, deposition topic 18, they said just Dr. Spencer. Oh, I think that one was pretty well covered.

AH, you know, they say he's going to identify documents. They never told us. Would you like me to continue, your Honor? It's getting -- I have a one o'clock hearing. It's getting late. I could just move this into evidence, or move this into the record, the chart, or I'll be happy to continue, if you'd rather.

THE COURT: No, no, you needn't continue. It's up to you. But the one o'clock hearing, where is that?

MR. CLEMENT: With Magestrate Shwartz.

THE COURT: Okay. How do you want to handle that, folks? I'm addressing the entire -- do you want to be heard in response, Miss Masurovsky? I mean, I'm going to need a minute, I think, to be honest with you. I had a decision of some sort prepared, but you come forward with a lot of new information, hundreds and hundreds of pages, and I'm doing everything on sort of an overnight basis. So do you want to take a break and then have the lawyers who need to go? It's not only you, is it?

MR. CLEMENT: It's Mr. Calmann as well.

THE COURT: Others have to go to Magistrate Judge Shwartz, and then continue, assuming that we still have the services of --

MS. MASUROVSKY: Your Honor, for Lilly, I believe I could respond fairly quickly to the points, if we can continue for a few minutes. We'll do whatever the Court prefers, obviously.

THE COURT: Okay. I'm trying to say -- I want to give -- given the timeframe, I think I intend to issue a real opinion, or at least to supplement my opinion when I'm done with this. But I want to give you my decision and get you, given the timeframe, so that you know it, and then I'll supplement it as soon as I can with a formal written opinion. But I'm not sure I can do that by one o'clock. We'll see. So you needn't continue with the A through --

MR. CLEMENT: Right.

THE COURT: -- G. You might want to address one thing for me, though, which is, it seems to me there's a full panoply of objections to this testimony that's improper, evidentiary, some of them substantive. The real question is, what is the prejudice by having him attempt, for example, some things that you don't quarrel with, you can't really quarrel with, "I was the head of the department, and we took these steps," period. You yourself said that before.

MR. CLEMENT: The prejudice?

THE COURT: What's the prejudice if that's the scope of the testimony and you're afforded an opportunity to take the deposition?

MR. CLEMENT: Well, I think the prejudice is how do we rebut that? We can take the deposition. We can cross examination. A lot of what he's saying is expert testimony.

THE COURT: Isn't that addressed a different way? I mean --

MR. CLEMENT: If we can have a rebuttal, I guess if Judge Cavanaugh is going to let us have a rebuttal expert witness.

THE COURT: I don't think there's going to be expert testimony from this witness. I'd be very surprised about that.

MR. CLEMENT: I guess if there was no expert testimony from this witness, then --

THE COURT: Okay.

MR. CLEMENT: And the witness was limited I think to certain areas where we're not -- I think the Tollefson area, the areas where the Tollefson stipulation -- I don't think he should be allowed to testify to that at all. I think we entered a stipulation.

THE COURT: Yeah, that's an argument, once again, I'm hearing for the first time today. I read your brief.

MR. CLEMENT: It's in our brief.

THE COURT: It was in your brief, the Tollefson --

MR. PARKER: No.

THE COURT: I read that brief about four times. I hear you. I think there's many objections to the testimony.

But, okay, not that one, at least I didn't see it there.

MR. CLEMENT: But, in any event, we would like to preserve all our evidentiary objections, hearsay, before Judge Cavanaugh, and all of those types.

THE COURT: There could be no other way.

MR. CLEMENT: And I'd like to move into evidence, or into this hearing, the record of this hearing, the chart and the note book. And their confidential information, I'm not sure if there's confidential, we'll file a motion to seal it, if that's okay with your Honor.

THE COURT: Yes, of course. There's no problem with that. I mean, what about what has been said on the record? I wouldn't worry too much about it, it's all generic talk on the record. But keep in mind, this is open, we didn't seal the proceedings.

MR. CLEMENT: I understand, your Honor.

Okay. If Miss Masurovsky can finish by one, I would sit down.

THE COURT: Okay.

MS. MASUROVSKY: May I, your Honor?

THE COURT: Sure.

MS. MASUROVSKY: Thank you.

A couple of points. As we indicated at the beginning, we were responding to their coming forward with their contentions on this non-enablement defense, so that is again in

the context of the burden of proof being on the defendants to show us what their cards were. We had no validity, quote unquote, evidence to come forward with in that interrogatory request until we saw what their case was. And when they did articulate their case, contrary to what counsel said, there was no holding that Lilly could not submit post-filing evidence. That's not what the Rasmussen case stands for. It simply held that in that particular case, there was no post-filing evidence offered. Whereas here, your Honor, we had, and we continue to believe, we certainly believed, until Judge Cavanaugh told us otherwise, that our post-filing evidence would suffice to show the end of the question. And it was only after that became an issue that we were in a position to have anything to supplement, and we did that promptly. We effectively supplemented our interrogatory answer in our opposition briefing on the reconsideration -- excuse me, on the supplemental briefing in response to the Judge's -- to Judge Cavanaugh's request that we address this case.

Your Honor, we had no other position to offer. We thought that was a complete defense -- a complete answer to what they had come forward with. They come forward with certain evidence. We responded. When the Federal Circuit came down with its 318 decision, Judge Cavanaugh recognized its importance and asked for supplemental briefing. At that point we came forward with a supplemental response. And we didn't

put it in the form of a formal supplemental answer to interrogatory, but in general the commentary to the federal rules is if you make your answers known, you don't have to formally do it in the context of the same paperwork all the time. In other words, just like when a witness is identified during a deposition in efficient ways, if you give an answer in a letter, parties are given supplemental information in a letter, it doesn't have to be in the form of an interrogatory, formal supplemental interrogatory answer. At least that's what the practice was in this litigation between these parties. We've produced documents which answered their questions, and we didn't specifically refer to them, and they didn't specifically complain. They complained about lots of other things. So respectfully, when we said they are in the documents, that's sufficed in this case.

Finally, the issue of the documents and the IND that they want to take back because it does show how people of skill in the art at the time believed it was a promising treatment for ADHD. All of those are addressed fully in the briefing that they filed, which is their document 582-1, and our opposition response. I won't belabor it, but I believe we've adequately addressed their arguments with respect to the 30(b)(6) notice, and the very narrow topic on which they are complaining about the preparation and filing of the Mass General IND. I believe that's fully addressed in our briefing.

Finally, your Honor, again, while the words that Dr. Paul would use at his testimony are best addressed by asking him, himself, we did our best to lay out a road map for them so that -- in a deposition they can ask very pointed questions. They're obviously free to ask anything they want. Obviously all the concerns they have that they articulated today, would be alleviated if they had already taken his deposition, or would take his deposition, because they can ask him, himself, and anything they think he's going to say, for example, speculate in their paperwork that he would say Dr. Heiligenstein was this or that. They can ask him.

THE COURT: I don't know how that would be admissible any way, but that's fine.

MS. MASUROVSKY: And I don't think we intend or have any plans for him to, in any way, contradict the stipulations that have been filed in this case at all. He is not going to -- there's nothing being offered about what Dr. Tollefson said that would violate that stipulation in any way.

Again, the issue here is can he replace Dr. Watanabe, given that we had an entirely unexpected situation and worked as quickly as we could to replace him, to find a replacement for him? And will that prejudice be cured by putting him -- putting the defendants on equal footing as if Dr. Watanabe could come to court? We respectfully submit, under the In re: Jacoby and similar cases, that that should be the result in

this case as well, your Honor. Thank you.

THE COURT: Thank you.

I just want to respond quickly. I feel I must, once again, you seem to be responding to their contention -- their contentions came out late 2008 regarding the unexpected death came out, what, in October, November, 2009? So you have five or so unexplained months. There's no question that as far as I'm concerned, the interrogatories, what I saw this morning in terms of the interrogatories and the document request, and the 30(b)(6) notices were not properly responded to and were not updated in concept because in your briefing, your new theory came across, I don't believe that's tantamount to what is listed in Rule 26(a) and 26(e) about an initial disclosure update. I just want to make that clear.

So, I mean, to the extent there was a gamble here in terms of not putting forward certain information until there was a certain decision, I think on some level the Court would have to decide who should bear that risk. But, in any event, I need a few moments and then I'm going to give you an abbreviated decision on this. And then I'm going to supplement that hopefully in the next day or so, if I can, with a legal written decision, but I need a minute to get that together.

Do you want to wait? Shall we see? Should I call Judge Shwartz?

MR. CALMANN: That would be most appreciative, Judge.

MR. CLEMENT: I would appreciate that, Judge.

THE COURT: I'll see if she can wait and get you out of here. Give me a minute.

(Recess)

THE COURT: I spoke to Judge Shwartz, and she's happy to wait for you folks for a few minutes. I'm not going to be too long.

MR. CLEMENT: Thank you, your Honor. Much appreciated.

MR. CALMANN: Thank you, your Honor.

THE COURT: All right. Before the Court is the motion to exclude Dr. Paul as a witness for failure to update initial disclosures, and as we heard with far more detail today and identified in response to numerous interrogatories and other discovery requests. I'm going to go through things in a very general format, and give you my basic decision, which will then be supplemented pursuant to local Rule 52.1, which permits the Court to supplement an opinion. So I'm going to speak in rather general terms.

Rule 26(a) and 26(e) deal with initial disclosures and provides that they must be made, which would certainly include people with knowledge, and that they must be updated, timely updated as required. And there is some exception language in the rule as well to the extent that the persons dealing with initial disclosures are otherwise identified in discovery. It

may not need a formal supplementation. This is very basic law.

There is also a law from this District and Circuit that explain, especially in a patent case, that in order to qualify under the otherwise been made known disclosure language, the alleged disclosure must be clear and unambiguous. So disclosures during discovery that are not facially apparent and require the drawing of further inferences are insufficient to meet the requirements of Rule 26. Ultimately this determination is made on a fact in a case specific basis. Rule 26(a) and (e) work together with Rule 37, Federal Rule of Civil Procedure 37, which provides that the party is not allowed to use information or witness, or to supply evidence on a motion and hearing where the trial, if there was a failure to disclose and update, unless the failure was substantially justified and was harmless. So Rule 37 provides a strong inducement for disclosure of Rule 26(a) material as well as updating discovery responses. Because failure to comply with Rule 26(a) may preclude a party from using any information or witness that's not disclosed. When I supplement this, I'm going to give further authority, far more detail.

Exclusion under Rule 37 is not automatic. There is discretion with the Court. And in order to make the decision, the Court, the Third Circuit has identified four factors to consider whether failure to disclose or supplement warrants exclusion of evidence: The prejudice or surprise of the party

against whom the excluded evidence would have been admitted; the ability of the party to cure the prejudice; the extent to which allowing the evidence would disrupt the orderly and efficient trial of the case and other cases in the court and bad faith or willfulness in failing to comply with a court order or discovery obligation.

It is true, as was mentioned here today, that exclusion of evidence is an extreme sanction, not normally imposed, absent a showing of willful deception or flagrant disregard of a court order by the proponent of the evidence. Alternative sanctions are available and should be considered as well as the importance of the potentially excluded evidence, prior to prohibiting the use of a witness or evidence at trial. We have a rather fact specific and detailed and somewhat unusual scenario before us, much of which was discussed on prior occasions and today. Indeed, today I received hundreds of more pages of materials, having received hundreds and hundreds of pages in just the past few days. We're on the eve of trial and we're doing this as quickly as possible. Virtually on an expedited basis. So without reviewing the whole factual scenario, with that rather general description of the applicable law, I'm going to make certain findings and make -- and doing analysis under that law, an outline form, and provide you with my decision on this motion.

First, I find that the initial disclosures and the new

ones to the Court, to some extent, and numerous discovery requests, were not timely updated as required. And despite plaintiff's explanation for same, which I take at face value, there's no legitimate excuse for not updating the initial disclosures and the discovery responses.

To the extent that Dr. Paul is really a substitute for Dr. Watanabe, the tragic death of Dr. Watanabe occurred ten months ago. To the extent that the plaintiff had to wait for the contentions of the defendants, that was in 2008. And to the extent, which I don't believe is a legitimate reason at all, but to the extent the Court's decision, summary judgment of reconsideration was a reason, even that was months ago and there's no excuse for waiting until April 5th. And I should say that what I learned today, it appears while there was an updating of the initial disclosures to include Dr. Paul as a witness, it does not seem to be, to this day, to have been an updating or supplementation of the numerous discovery requests that I first saw today. I could be wrong about that because I don't know if the defendants -- if the plaintiff had a chance to respond to it, or even saw it before today.

Having found that Dr. Paul was -- that the disclosures were not updated as required, the Court does find that Dr. Paul was identified in depositions in a general way as one or two or three people who were involved in the neuroscience department and had some knowledge of the development of atomoxetine, once

again, in a very general way that Dr. Watanabe was initially identified. I'm not sure when, the exact date, his description of knowledge of certain aspects of the development of Strattera. I ordered a proffer be made, and there was much argument about the proffer, and I still have questions about the true meaning of the proffer and the true extent of it. And we had a discussion on the record about it today. But at least some of the proffer, very little, I should say, but some does overlap with Dr. Watanabe's description. Maybe one or two sentences. For example, in the proffer it does say that Dr. Paul would testify about the development of Strattera. Of course there are many other things described in the proffer. So I do find that Dr. Paul was identified as a person with some knowledge related to the case in the depositions, but certainly was not sufficiently disclosed or identified as to the topics in his proffer.

And as we learned today, indeed in response to discovery requests, the topics in this proffer do not seem to have been responded to sufficiently with respect to some of those discovery requests, keeping in mind that exclusions are an extreme sanction. And considering Rule 37, I consider the Newman factors or the Meyers factors. Newman is another Third Circuit case 60 F. 3d 153. They're the same four factors to be considered when you find that a witness, or evidence has not been disclosed, and you're considering the remedy versus the

prejudice to the defendants. I find that the defendants have been prejudiced to some extent by the late disclosure. The obvious prejudice is having to do this motion practice, being distracted on the eve of trial. It maybe that there's more prejudice, but it's really impossible to tell.

The other prejudice that the defendants, the only other prejudice that the defendants identify, which to some extent could be legitimate, is based on evidentiary issues. In other words, if, for example, Dr. Paul was permitted to testify as an expert, they would be prejudice in that they may not have an expert to refute Dr. Paul. So most of the other claims of prejudice are based on evidentiary objections.

Can the prejudice be alleviated is the second factor? And the Court believes that the prejudice that it is aware of can be alleviated in terms that I will describe shortly. Will it disrupt or adjourn the trial or interfere with other cases? And the answer is no, the trial will not be adjourned, certainly for any reason that I can think of, absent -- certainly not for this reason.

Bad faith is the final factor. I can't, based on what I've heard, make a finding of bad faith. I'm troubled by some of the representations that have been made to the Court. I think parties, in an air of desperation, I think there is a slight exaggeration on certain things. And I understand the stakes in this case, but I'm not prepared to find bad faith.

So Dr. Paul will not be automatically excluded for the late disclosure.

Dr. Paul may indeed be excluded or certainly limited on evidentiary or other substantive grounds. And all of these admissibility issues will be handled by District Judge Cavanaugh, the trial judge in this case. If plaintiff intends to use Dr. Paul as a witness, it must immediately produce him for deposition and pay all costs and fees of the deposition, including the fees for one lawyer for each defendant to appear at the deposition, not to prepare for the deposition, but to appear at the deposition, at a rate, arbitrary rate of $400 per hour. I believe this is fully justified as an alternative to Rule 37 sanction, and I think that it is fully justified by the serial failure to update initial disclosures and discovery responses by the -- by waiting until the last minute to make Dr. Paul available, or to make his presence known. Not his presence, but the intention to use him known. And depending upon the deposition, defendants may be able to, certainly will be able to supplement or have their witnesses address anything new, anything that would be admissible.

Next, should the extent that any of Dr. Paul's testimony is admissible or admitted, it must be strictly limited to what is in the proffer.

Next, an essential part of my decision, not excluding him, that Dr. Paul not be permitted to offer any expert

testimony. It's my view that this is not even a close call. There's been no compliance with Rule 26, no expert report, no expert disclosures. And if he were permitted to give expert testimony, then defendants would have a right to have experts perhaps hire new experts and that would reshuffle the factors and not alleviate the prejudice.

Further, it's my view that Dr. Paul should not be permitted to offer lay opinion testimony. This issue is going to be up to Judge Cavanaugh. But having spent so much time on this, I'm including my strong view that this shouldn't be permitted. The Third Circuit, as well as other courts, have noted global preclusion of any kind of lay opinion on a specialized or technical subject, and I'll expand on that law further.

Next, nothing here in any way meant to encroach on Judge Cavanaugh's absolute and total control of the trial.

Finally, although it is entirely the province of Judge Cavanaugh, having spent a tremendous amount of time reviewing the papers in this case, and especially the defendant's opposition papers, which to a great extent rely on evidentiary and other problems with the proffer of Dr. Paul, I'm simply going to state my opinion that there would appear to be very serious substantive and evidentiary impediments to the admission of much of the testimony outlined in the proffer, which could include relevancy, hearsay, speculation, testimony

which is lay opinion, either expert opinion, failure to comply with other discovery -- strike that. And I included that in my own opinion, even though not controlling, certainly not fully briefed before me, so that the parties can at least take that into account in determining how to proceed with this.

I'm going to enter an order, counsel, and then I'm going to supplement my opinion with detail, subject to Rule 52.1. If you proceed with this deposition and with this witness, I expect it to be done on a professional basis. No games of any kind. I will make myself available to address any problems.

MR. CLEMENT: Your Honor, just one other -- the location of the deposition, would you prefer it to be in Newark, since we'll all be --

THE COURT: I'm going to ask that you confer in good faith and the moment you have a dispute, you call me.

MR. CLEMENT: Thank you, your Honor.

THE COURT: Is there anything I need to decide right this minute?

MR. PARKER.: Your Honor, this is Tom Parker, from Mylan. Your Honor indicated in his conclusions that there be no expert opinion or lay opinion testimony. We assume what your Honor said is he could testify as to what's in his proffer, we assume you mean excluding anything that goes to expert opinion or lay opinion testimony.

THE COURT: What I'm saying to you is I'm going to do the best I can under the circumstances, I'm not the trial judge, in terms of making the determination of what expert testimony is or isn't. To the extent that any of this is admissible, to the extent that it's allowed, it still must be within the proffer. In other words, it can't go beyond that proffer.

Certainly part of my ruling is that he should not be permitted to offer expert testimony, but there's no way you've given me -- I can't simply sit here, I don't know what the question and the answer are going to be. You're going to have to take that up with the, you know, trial judge. I can't rule on something specifically. The proffer is vague. And indeed we don't have questions and answers, and it's too late, I don't have the time. I don't know what you're asking. Me, I think you got the right idea, that is my intention. And I'm going the best I can on short notice.

MR. PARKER: Thank you, your Honor. And I apologize if I missed this.

With respect to the evidentiary objections that we have, that were part of the submissions, do we do that by separate submission to Judge Cavanaugh, or do they stay within the papers?

THE COURT: I can't answer that. I will say that they're all preserved.

MR. PARKER: Thank you.

THE COURT: And I think you should take a practical approach at this point. You have put a lot of paper before Judge Cavanaugh. It maybe best to address it at trial, I'm just not sure. It doesn't seem very complicated to me, but that's up to you folks.

Anything else? Thank you.

(All parties say thank you)

(Matter concluded)